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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,952	11/27/2001	Michael G. Walker	PB-0016 US	2398

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,952	WALKER ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the c ver sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4-8 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-20 are at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1, 2, 3, 9, 10 and 11 and SEQ ID NO: 7, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that claims 4-8 of Groups II and III are methods of making and/or using the products of the claims of Group I that depend from and are limited in scope to the products of those claims and could therefore be examined together with the claims of Group I without undue burden. Applicants arguments with respect to the restriction of Groups I-III is not found persuasive, because as was previously stated, Inventions I and inventions II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Group I can be used in a materially different process such as one in which the are used to synthesize the encoded proteins. Because these inventions are distinct for the reason given previously and above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicants reference to the rejoinder of claims drawn to methods of making and/or a methods of use of allowable product claims is noted, and will be dealt with at the time that allowable product claims have been determined.

Applicants further submit that the Examiner's requirement for applicants to elect a single sequence for examination relative to the claims of Group I is improper and applicants submit that the MPEP 803.04 supports applicants position. Applicants specifically submit that since claim 1 contains less than ten sequences, all sequences of the combination should be examined. Applicants argument is not found persuasive. Applicants are reminded that with respect to claim 1 which requires the combination of SEQ ID NOs: 1-9, all of the sequences will be considered/examined. However with respect to the remaining claims, 2, 3, 9, 10 and 11, of Group I, only SEQ ID NO: 7 the elected Group, will be examined based on the undue burden caused by the search and examination of those sequences claimed in addition to SEQ ID NO: 7, (i.e. SEQ ID NOs: 4 and 6). Applicants are reminded that a complete and proper search the elected subject matter involves the search of not only the referred to nucleic acid sequences using a number of different multiple databases, but of also the encoded amino sequences using a number of different multiple databases. Further these searches take a considerable amount of time that is dependent on the type and length of the sequences and the various embodiments reasonably considered to be encompassed by "said sequences".

Applicants comments regarding the examination of SEQ ID NOs: 1-6 are unclear as claims 2, 3, 9, 10 and 11 are currently drawn to SEQ ID NOs: 4, 6 and 7, and claim 1 is drawn to all of SEQ ID NOs: 1-9.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-8 and 12-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 9.

Priority

Applicants statement regarding claiming the benefit of provisional application 60/253,425, filed 27 November 2000, is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosures, Paper No. 7, filed 3/5/2002, is acknowledged. Those references considered have been initialed.

Specification

The disclosure is objected to because of the following informalities:

Applicants claim to priority in the first line of the specification recites "60/253425". It is suggested that this be amended to 60/253,425".

Figures 1 and 2 list sequences which do not appear to have associated with them a sequence identifier. Further, when a sequence is listed in a drawing, the sequence identifier for that sequence must also be listed in the drawing or in the description of the drawing.

MPEP Section 2422.02, The Requirement for Exclusive Conformance; Sequences Presented in Drawing Figures states: "...It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

As discussed below under 112 second paragraph rejections, applicants definition of a cDNA as listed on page 5, lines 17-20, which states "cDNA refers to an isolated polynucleotide, nucleic acid molecule, or any fragment or complement thereof..." is objected to because it is contrary to what is understood in the art. One of skill in the art understands that a "cDNA" refers to a "complementary DNA" (See Steadmans Medical Dictionary, 26th Edition, published by Williams & Wilkins 1995, page 297). This understanding is contrary to applicants definition.

Appropriate correction is required.

Claim Objections

Claims 2, 3 and 9-11 are objected to because of the following informalities:

Claim 2 (claims 3 and 9-11 dependent form) contain non-elected subject matter (i.e. SEQ ID NOs: 4 and 6).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (claims 3 and 9-11) dependent form) is indefinite in its reference to "A cDNA" given the definition of "a cDNA" listed on page 5, lines 17-20, which states "cDNA refers to an isolated polynucleotide, nucleic acid molecule, or any fragment or complement thereof..." The claim is indefinite in that while one of skill in the art would know that a "cDNA" refers to a "complementary DNA" (Steadmans Medical Dictionary, 26th Edition, published by Williams & Wilkins 1995, page 297). This understanding is contrary to applicants definition and thus those claims which refer to this term are confusing and vague. Is it applicants intent to claim an isolated polynucleotide, nucleic acid molecule, or any fragment or complement thereof which includes ribonucleotide molecules or is applicants intent to claim a cDNA?

It is noted that "the complement" of a cDNA is interpreted by the office as defined by applicants specification, page 5, line 22-25 as "a nucleic acid molecule which is completely complementary to the cDNA over its full length and which will hybridize to the cDNA or an mRNA under conditions of high stringency".

Claim Rejection(s) - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claim 1 is drawn to a combination comprising a plurality of cDNAs having the nucleic acid sequences of SEQ ID NOs: 1-9 and the complements of the nucleic acid sequences of SEQ ID NO:s 1-9. Claims 2-11 are drawn to a cDNA comprising a nucleic acid sequence selected from SEQ ID NOs; 4, 6 and 7 and the complements thereof and compositions, vectors and host cells comprising said cDNA and methods of expression of said cDNA.

The claimed cDNA compounds are not supported by a specific asserted utility because the disclosed use of the nucleic acid is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence being claimed. Further, the claimed cDNA compound is not supported by a substantial utility because the specification states only that the cDNA compounds are useful to screen for ligand molecules which specifically bind to the cDNA. Once such a ligand molecule is obtained, the ligand molecule would be used in conducting research to functionally characterize the cDNA and the encoded protein. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility.

In this case none of the ligands or proteins that are to be produced as final products resulting from processes involving the claimed cDNAs have asserted or identified specific and substantial utilities. The research contemplated by applicants to characterize potential ligand and protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the encoded proteins or associated ligands or the mechanism in which proteins or ligands are involved does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the cDNA compounds such that another non-asserted utility would be well established for the compounds.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9-11 are ejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed above under the rejection under 35 U.S.C. 101, since the claimed invention is not supported by either a specific and substantial asserted utility or

a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

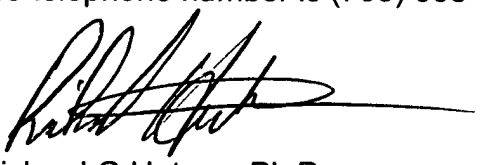
Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh